DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Orlando, FL 32809

Food and Drug Administration 7200 Lake Ellenor Drive

D14 20 B

CERTIFIED MAIL RETURN RECEIPT REQUESTED

Ref: Customs Entry No. PX4-0014444-8

Product: Cantaloupe Melons

WARNING LETTER

FLA-98-25

February 3, 1998

Mr. Ross Schmidt Import Manager Soltech, Inc. 1751 S.W. 8th Street Pompano Beach, Florida 33069

Dear Mr. Schmidt:

The Food and Drug Administration (FDA) attempted to examine a shipment of cantaloupe melons offered for entry into the United States by your firm on December 2, 1997, under the above referenced entry number, and found that the shipment was not available. Regulation Title 21, Code of Federal Regulations (CFR), Part 1.90, requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. requested the U. S. Customs Service (Customs) to order redelivery of this shipment (copy enclosed).

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of future shipments. It is your responsibility, as the importer, to ensure that imported products meet all requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

We request a response in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the recurrence of the violation. In addition, you should inform Customs and FDA if and when redelivery accomplished.

Mr. Ross Schmidt Page 2 February 3, 1998

Your written reply should be addressed to the Food and Drug Administration, Attention: Paul R. Bagdikian, Compliance Officer, P. O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,

Douglas D. Tolen

Director, Florida District

Enclosure